Seattle Cancer Care Alliance

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Photopheresis Technical Challenges

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Better together.

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No relevant disclosures

Therakos® CellEx® Photopheresis System

For technical challenges and troubleshooting:

- **Call Customer Support**
- **Use the Reference Ring**
- **Read the Operator's Manual**
- **Refer to Technical Bulletins**

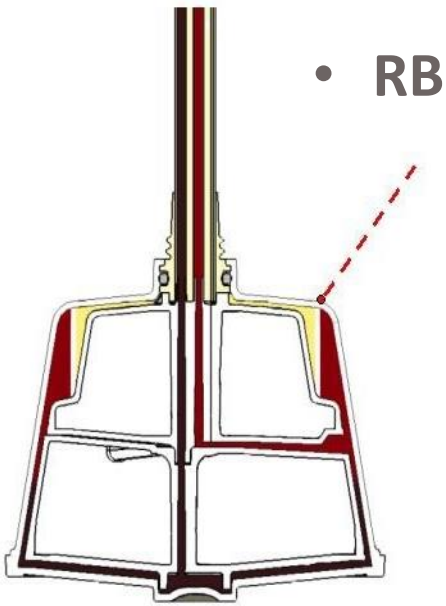
ECP @ SCCA : Managing challenges

- Common Alarms
- Procedural Kit Issues
- Other Challenges

Common Alarms

Red Cell Pump Alarm

- Incorrect interface position: high or low
- RBC Pump cannot modulate interface



Red Cell Pump Alarm – Interface Low

Cause

- Lipemic plasma[1]

Corrective Action

- Decrease bowl optic sensor
- Take action quickly / before alarm

Prevention

- Low-fat diet / meal timing
- Hold immunosuppressant meds
- Ok to do nothing if ready to take swift corrective action

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #04

Red Cell Pump Alarm – Interface High

Cause

- Slow / intermittent blood flow[1]
- High platelet count[1]

Detection

- Watch Bowl Optic: < 150
- Watch RBC pump: continuous rotation

Corrective Action

- Stop the bowl – won't lose buffy coat

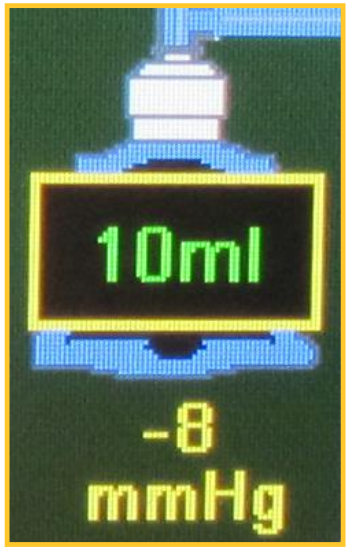
Prevention

- Improve venous access

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #04

System Pressure Alarm

- Increased Centrifuge pressure
- Centrifuge stops – bowl re-purge
- Buffy coat partially lost with re-purge
- Patient ECV temporarily increases 50 mLs



System Pressure Alarm - Centrifuge

Cause

- Air, ↑platelets[1]
- Kit manufacturing

Corrective Action

- Check for air
- ↑ Whole Blood Processed Target volume – judgement call

Prevention

- Resolve Red Cell Pump Alarms early
- Use ↑ AC Ratio
- ACD-A, Aspirin?
- Complaint to Therakos

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #05

Procedural Kit Issues

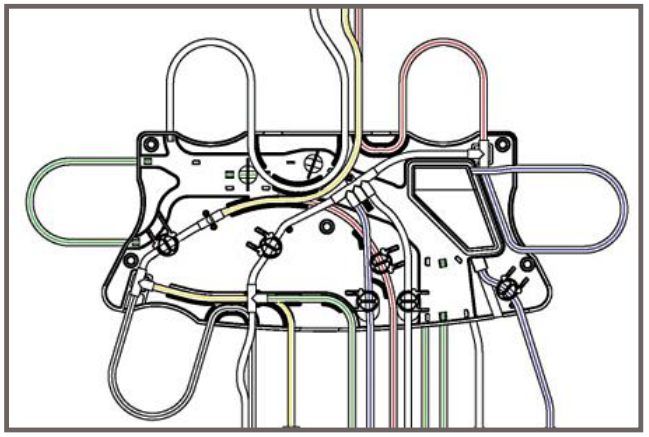
Kit Defects @ SCCA

- Tubing lines misrouted
- Parts incorrectly / poorly welded
- Material weakness

SCCA Cellular Therapy Quality Department directive:

inspect ALL kit parts prior to loading

Pump Tubing Organizer



Defect

- Tubing misaligned / pinched
- Tubing misrouted

Consequence

- Return Bag contents to Treatment Bag
- Loss of buffy coat to Return Bag

Corrective Action

- Misrouted tubing – no solution at time of discovery
- Pinched tubing – success with very slow flow rates
- Inspect organizer prior to loading
- Complaint to Therakos

Treatment Bag

Defect

- Occluded Injection port
- Injection port welded outside of bag

Consequence

- Can’t inject methoxypsoralen
- Injected volume flows outside the bag

Troubleshooting

- Injection spike to free injection port
- Complaint to Therakos

Pressure Dome

Defect

- Membrane sliced

Consequence

- Blood leak post-procedure
- Breach of kit integrity

Troubleshooting

- Prophylactic antibiotics?
- Inspect membranes
- Technical Bulletin CLX #17[1]
- Complaint to Therakos

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #017

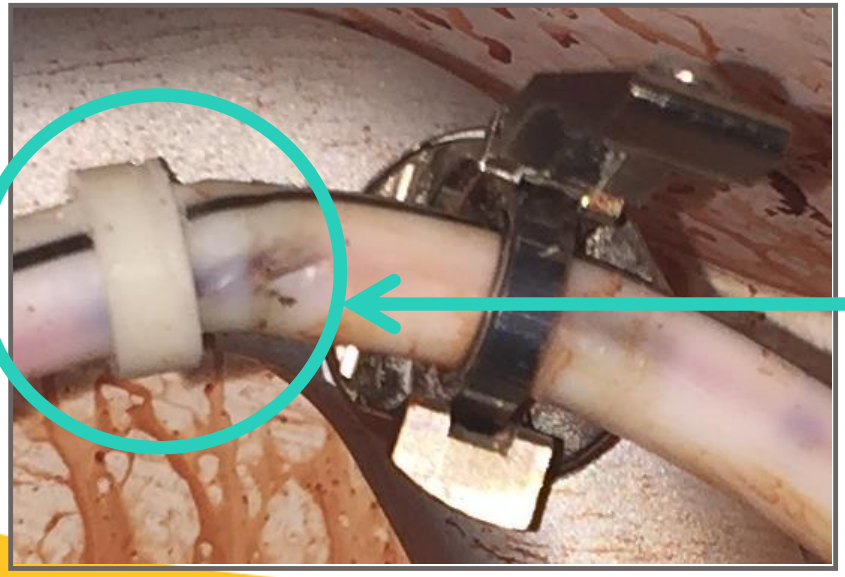
Drive Tube

Defect

- Upper Bearing Stop delamination

Consequence

- Drive Tube stretches → snaps
- Blood loss / Aborted Treatment



Drive Tube

Corrective Action

- Calculate blood loss using Technical Bulletin CLX#08[1]
- Can be operator error – ensure proper loading
- Complaint to Therakos

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #08

Centrifuge Bowl

Defect

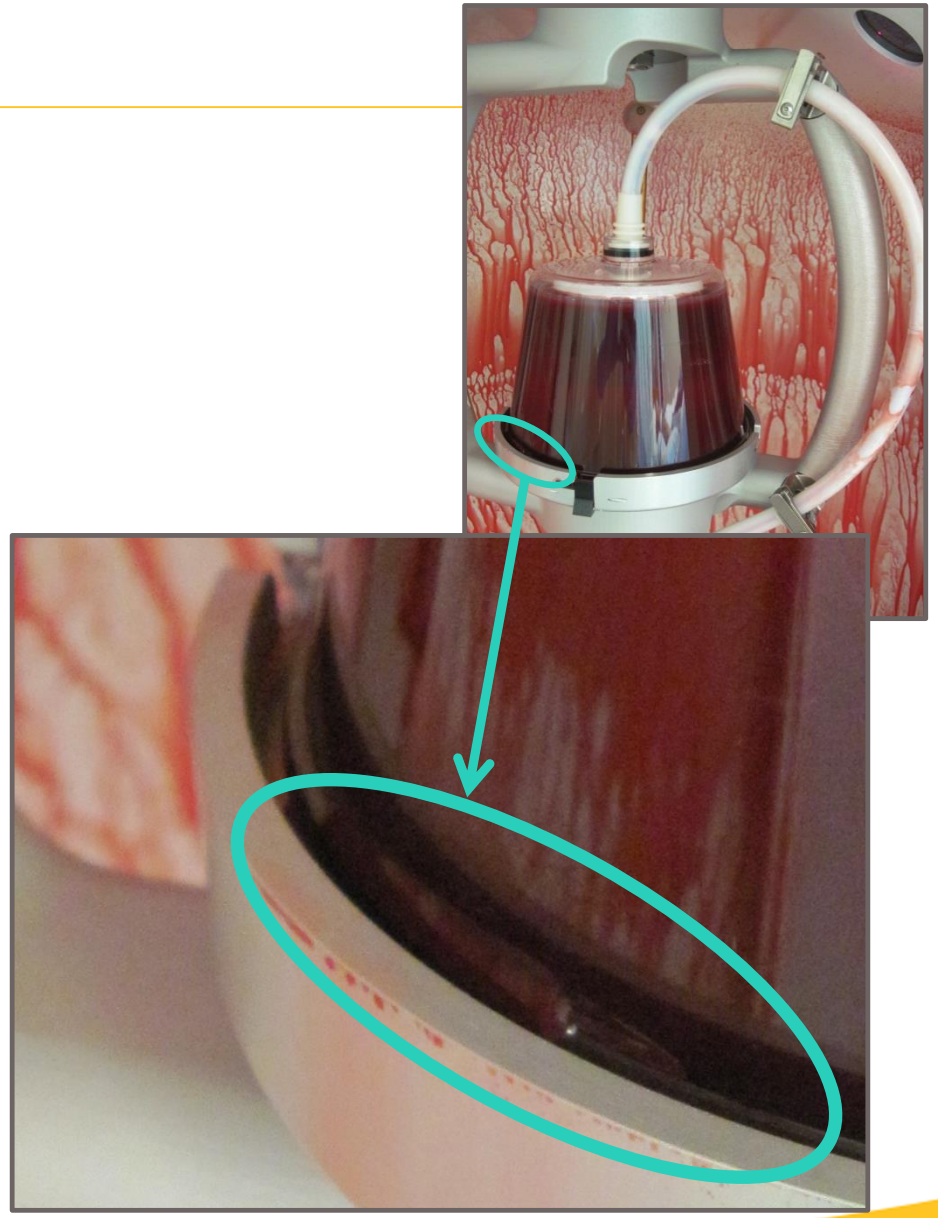
- Faulty weld at bowl joint

Consequence

- Blood loss

Corrective Action

- Calculate blood loss
- Technical Bulletin CLX#08[1]
- Complaint to Therakos



1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #08

Switched Fluid Lines – Not a defect, but . . .

Cause

- Operator error
- Poor tubing color-coding

Consequence

- Circuit blood clotting
- Abort procedure → blood loss

Corrective Action

- Report to Therakos
- Labeling / 2nd Check

Switched Fluid Lines

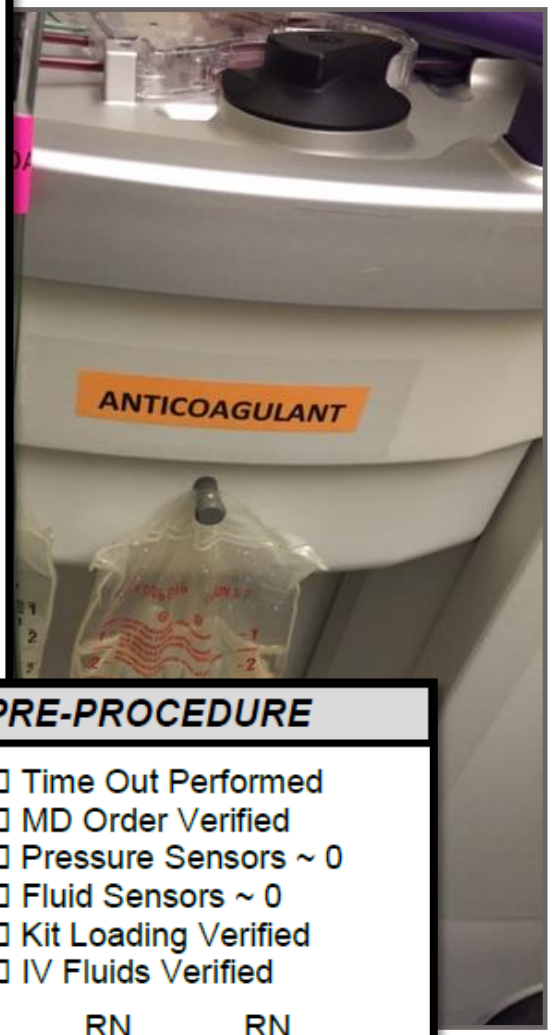
THERAKOS CELLEX PROCEDURAL KIT SET-UP: REMOTE SECOND CHECK

The nurse at SCCA reads the following to the nurse off-site.

The nurse at SCCA checks each item after the nurse off-site confirms correct configuration.

- ☐ The Centrifuge Bowl is securely seated on the Centrifuge Plate – the tabs are in the horizontal grooves
- ☐ The Drive Tube Bearings (metal rings) are seated **INSIDE** the Bearing Clamp Retainers – TOP and BOTTOM
- ☐ The Pressure Domes are securely attached – push dome arms outwards to ensure tight connection
- ☐ The Hematocrit Cuvette is sitting flush in the hematocrit sensor
- ☐ The Treatment Bag ("T" at top of bag) is hanging on the left Load Cell Hook, curved side to the left
- ☐ The Return Bag ("R" at the top of bag) is hanging on the right Load Cell Hook, curved side to the right
- ☐ The Anticoagulant Line (green stripe tubing) is spiked into the anticoagulant bag – bag on rear hook
  - ANTICOAGULANT label is attached to the anticoagulant line
  - Off-site RN: read-back solution name and expiration date
- ☐ The Saline Line (clear tubing – no color stripe) is spiked into the saline bag – bag on front hook
  - Off-site RN: read-back solution name and expiration date

Nurse off-site: document Remote Second Check on REP190 Treatment Summary by writing in name of SCCA second check nurse.



PRE-PROCEDURE

- ☐ Time Out Performed
- ☐ MD Order Verified
- ☐ Pressure Sensors ~ 0
- ☐ Fluid Sensors ~ 0
- ☐ Kit Loading Verified
- ☐ IV Fluids Verified

_____ RN _____ RN

Other Challenges

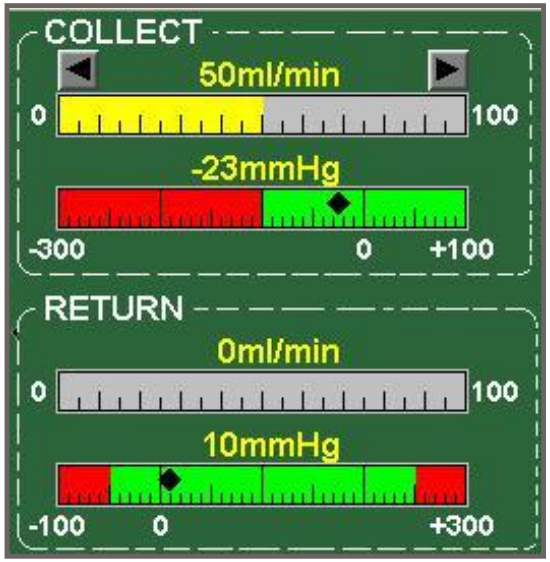
Positive Ending Fluid Balance

Cause

- All prime fluids delivered to patient
- Double Needle Mode, Purging Air: saline @ 5mL/min[1]

Consequence

- Single Needle Mode ± 370 mL
- Double Needle Mode ± 400-500 mL
  - ↓ flow rate in Purging Air = ↑ saline



Corrective Action

- No option for Single Needle Mode
- Double Needle Mode
  - Return Pump to 0 during Purging Air[2]

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415
2. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Section 10 Fluid Balance Management

Variable Fluid Shifts

Cause

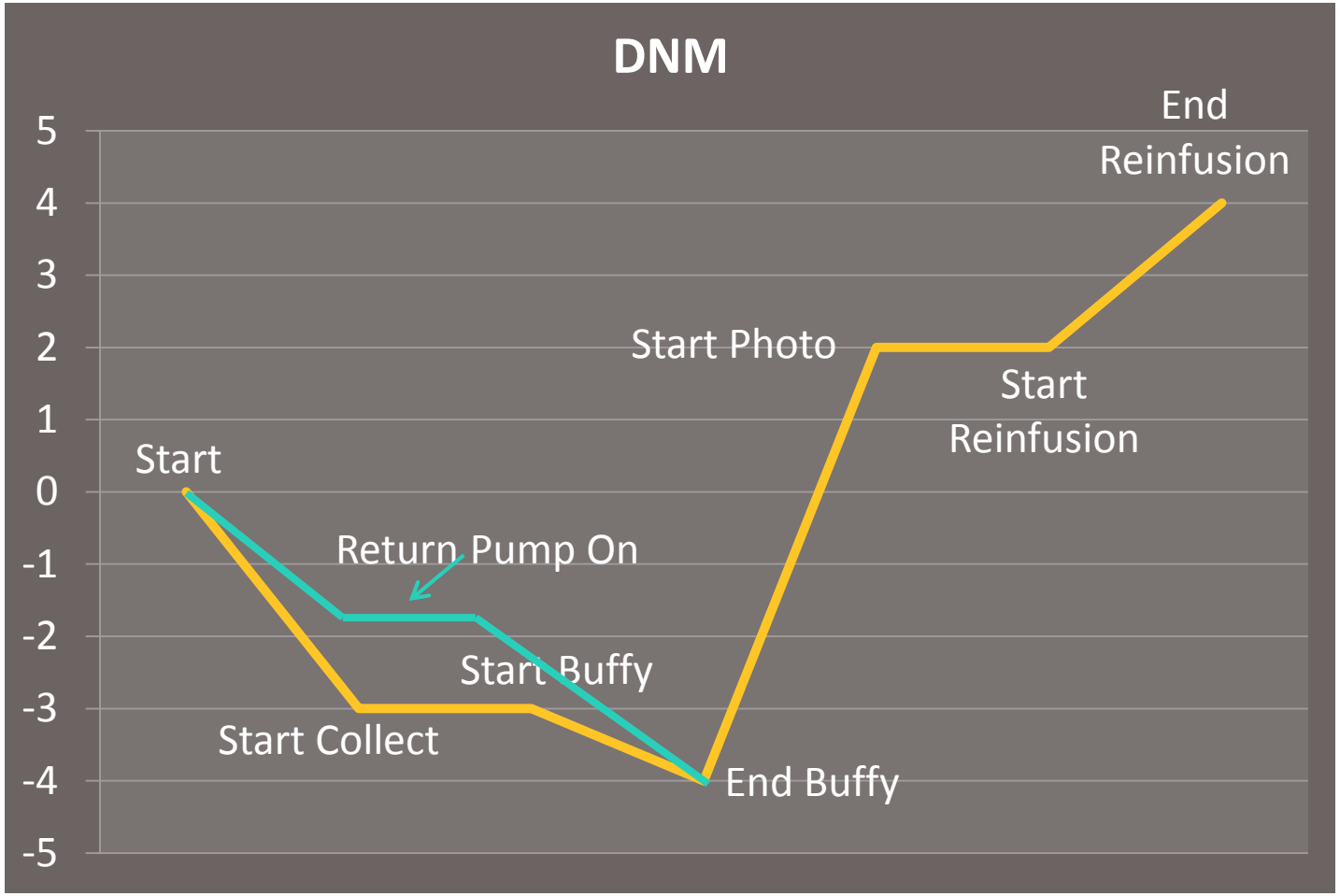
- ECV / fluid shifts during procedure phases due to discontinuous flow processing

Consequence

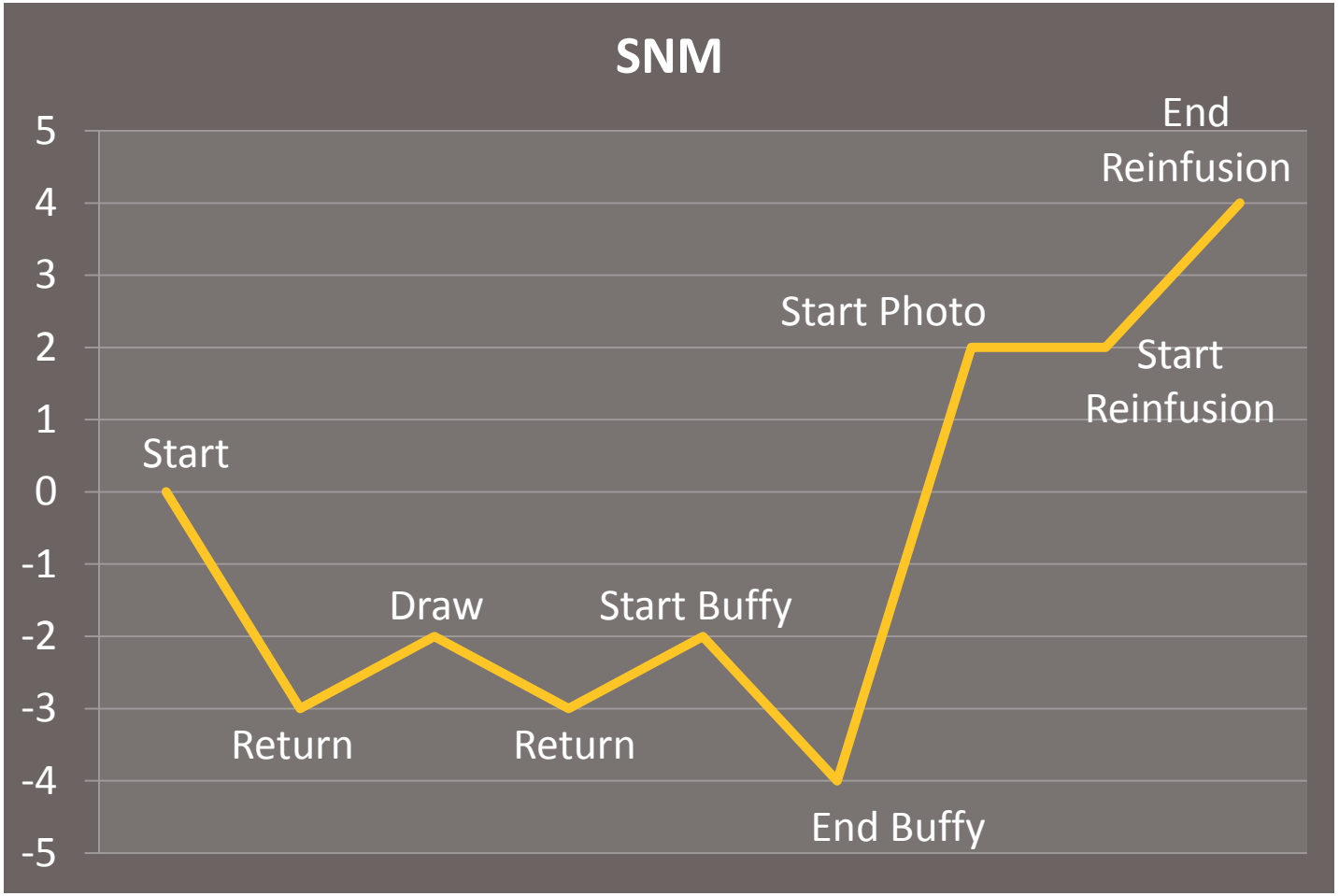
- Frequent, maybe rapid, fluid shifts in short time frame
- May be challenging for patients with cardio/pulmonary or renal impairment[1]

Crookston K., in: McLeod BC, et.al Apheresis: Principles and Practice, 3rd Edition 2010: 45-69

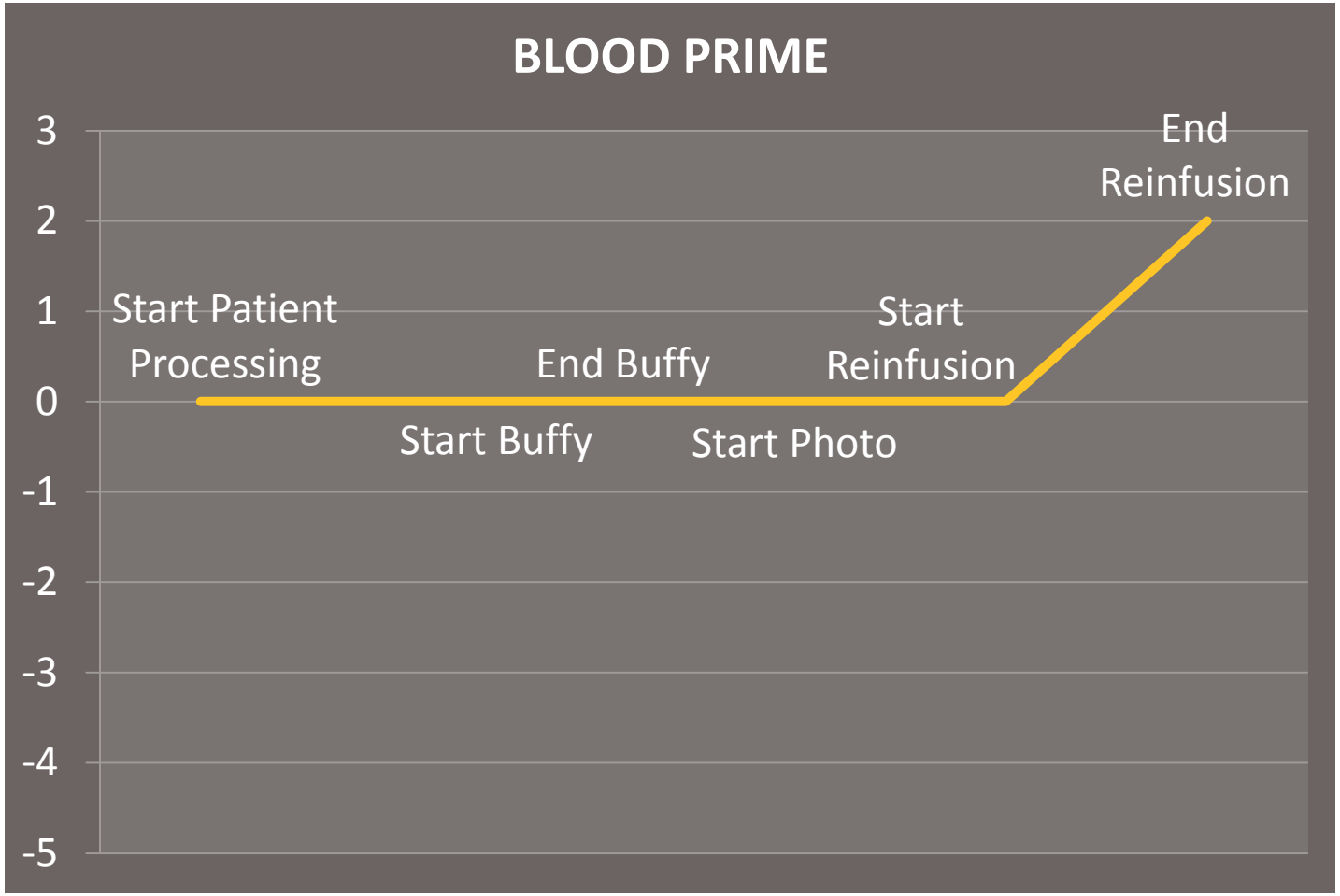
Fluid Balance – Double Needle Mode



Fluid Balance – Single Needle Mode



Fluid Balance – Blood Prime



Variable Fluid Shifts

Corrective Action

- Single Needle Mode – Return Bag Threshold 100 mL[1]
- Double Needle Mode – Return Flow Rate > Collect Flow Rate[1]
- Both Modes – Slow Return / Reinfusion Rates

1. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Section 10 Fluid Balance Management

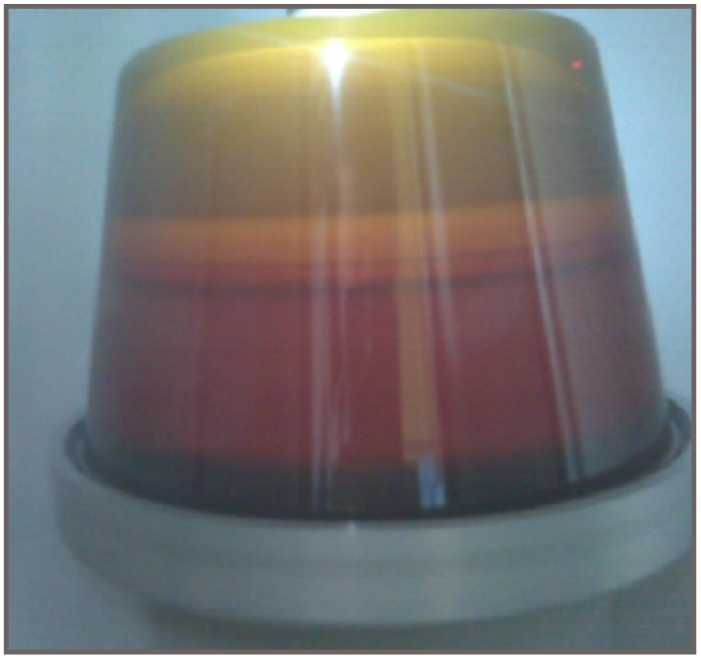
Abnormal Plasma – Bilirubin

Cause

- Bilirubin in plasma[1]

Consequence

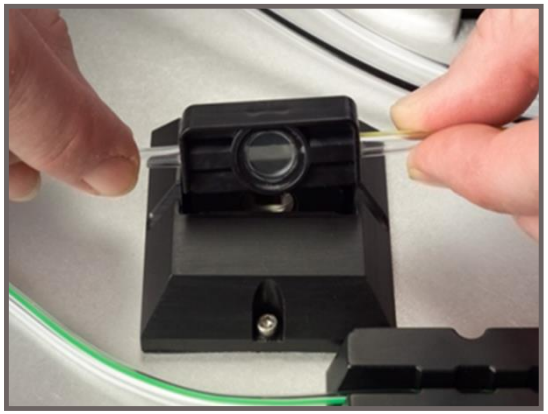
- Red Cell Pump Alarm – Interface Low[2]
- Hematocrit Sensor ends buffy coat collection early
- Partial or no buffy coat collected

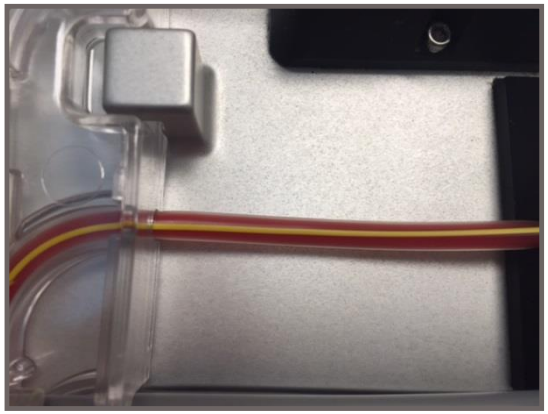


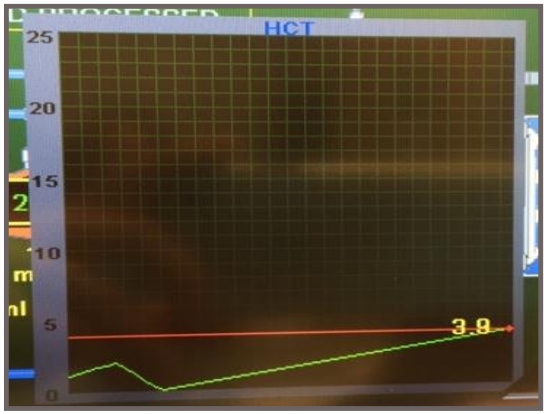
1. Chao N, et. al. Clinical Manifestations, Diagnosis, and Grading of Acute Graft-Versus-Host Disease, UpToDate, May 04, 2015
2. Therakos CellEx Photopheresis System Operator's Manual Rev. 5.0-1460415 Technical Bulletin CLX #04

High Bilirubin – Corrective Action

1. **Red Cell Pump Alarm** - lower Bowl Optic setting







2. **Remove Hematocrit Cuvette** prior to BUFFY COAT phase
3. **Replace Hematocrit Cuvette** when Buffy Coat appears consistent with **3-5% hematocrit**
4. Two minute PAUSE proceeds – remainder of procedure should progress as normal

ACD-A – Managing Citrate Toxicity

Challenge

- CellEx®: currently fewer problems with more anticoagulant
- Intermittent rate of delivery

Management @ SCCA

- Slow flow rates[1] – Return Rate MAX = 50 mL/min
- Pause flow, offer calcium-rich food
- Calcium carbonate 1 – 2 grams PRN pre/during procedure[2]
- Calcium gluconate 10% 1 gram bolus

1. Weber L, et. al. J. Clin. Apheresis 2012, 27: 13-14

2. Didehbani T, et. al. J. Clin. Apheresis 2012, 27: 22

Blood Prime @ SCCA

Following Therakos Operator's Manual for process

Practice Highlights:

- Trigger: ECV > 10%, weight < 25 kg
- ACD-A: @ 14:1 ratio
- Calcium Gluconate infusion: 20 mg/kg/hr
- Collect / Return MAX Rate: 30 mL/min
- Reinfusion Rate: 5-10kg = 3-5 mL/min, >10kg up to 25ml/min
- Whole Blood Processed: 1000 mL

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Thank you . . .
and good luck!

Better together.